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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,811	02/12/2002	Paul M. Lefebvre	GI-35	8854
23524	7590	08/09/2005	EXAMINER	
FOLEY & LARDNER 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			GORDON, BRIAN R	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/075,811

Applicant(s)

LEFEBVRE, PAUL M.

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7-12-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14 and 19-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14, 19-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 12, 2005 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed July 12, 2005 have been fully considered but they are not persuasive. As to claim 1 it is unclear as to exactly what applicant intends to claim (see 112 section below).

Furthermore, the examiner asserts valve 38 of Jones as disclosed below is equivalent to applicant's pump valve.

In view of applicant's amendment, the previous 102 rejection of claim 37 is hereby withdrawn.

### ***Claim Interpretation***

3. The preamble of the claims refers to the device as "a liquid chromatography sample injection system". While applicant is allowed to reference the device as so desired, it examiner asserts the preamble does not further limit the device as being structure of a liquid chromatography device, for the claims do not positively recite any further analytical elements such as a column to limit the device to such a system.

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Therefore, a device in any other field that meets the elements of device positively recited after the transitional phrase may be applied.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14, 27 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 14, it is unclear if applicant intends for the probe pump and source of dilutant to be considered as elements of the invention. The elements are referenced in relationship to the pump valve but not positively recited as elements of the invention. As such, the examiner interprets the claim as to mean the pump valve only has to be capable of being interfaced with those elements.

As to claims 27 and 37 it is unclear how the arms of the device interact to function with the probe.

Claim 27 in particular is drafted in manner to suggest the X, Y, and Z arms are in addition to the arm recited in claim 14 (4 arms). There is no support for the device comprises 4 arms as suggested by the claim language. Furthermore, it is unclear how the probe interacts with arms of claims 27 and 37. The examiner suggests amending the claim to include the probe holder and further amendments as suggest below in reference to claim 37.

The examiner suggests amend claim 37 as follows:

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(a) a probe drive system of an automated liquid handler; wherein the probe drive system comprises an X arm extending horizontally in an X direction; a Y arm slidably mounted on the X arm wherein the Y arm extends horizontally in a Y-direction and slides in the X direction; and a Z arm slidably mounted on the Y arm wherein the Z arm extends vertically in a Z direction and slides in the Y direction; and a probe holder slidably mounted on the Z arm to slide in the Z direction;

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 14, 19-22, 26, 29, 31-32, 35, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones.

Jones et al. discloses an apparatus which includes a sampling head adapted to be mounted at a sample pickup station. The head includes a hollow sample pickup probe adapted to be inserted into a sample container at the sample pickup station for extracting a given amount of fluid sample from the container. The pickup probe is

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movable between a first or sampling position and a second or retracted position by means of an air cylinder. A valve mechanism connected to the probe is operable on movement of the probe to the sampling position for connecting the probe to a device for withdrawing fluid from the sample container through the probe. The air cylinder not only moves the probe but also, and at the same time, operates the valve mechanism. In the second position the valve mechanism effects fluid connections for mixing a given amount of the fluid sample with another fluid and for simultaneously transferring the mixture to a receptacle (abstract).

When a sample arrives at the sample pickup or aspirating station where one of the sampling heads is located and assuming that the analysis calls for the sample to be mixed with a diluent or a reagent, the probe dips down into the sample, sucks up a quantity of sample, and then withdraws from the cup. During these movements, the diluent or reagent is first drawn into a pump, second, mixed with a specific volume of sample and third, delivered by means of a conduit or tubing to a reaction tube apart from the sampling head. All of this is done **automatically** after which the sampling head is ready for the next cup to come along.

The device comprises a **programming device 14 (controller)** for controlling the automatic operation thereof.

The sampling head 12 includes a **valve mechanism 16 (injector valve mounted on arm 56)** defined by first and second valve blocks 18 and 20 respectively, linearly movable (slidable) relative to each other between two valve positions, namely, a sampling position and a delivery position (loading and injecting positions).

The **probe 22** and the valve mechanism 16 the probe 22 is connected through the valve blocks 18 and 20 and a **sample loop 34** to a **sample pump 36** for withdrawing some of a liquid sample from the cup 24. The pump 36 is operated by a valve 38 (pump valve) connected to the sources 30 and 32 of pressure and vacuum and controlled by the device 14. In this way a given amount of sample is drawn, i.e., aspirated from the cup 24 and into the sample loop 34. At the same time, a **source 40 of reagent (pressurized source of liquid mobile phase/dilutant)** is connected through the valve blocks 18 and 20 to a reagent pump 42 which is operated by a valve 44 connected to the sources 30 and 32 of pressure and vacuum for filling the pump 42 with a quantity of reagent. The valve 44 is also controlled by the device 14.

When the valve mechanism 16 is in the second or delivery position, one end of the sample loop 34 is connected through the valve blocks 18 and 20 to the reagent pump 42. The other end of the sample loop 34 is then connected to a conduit or tubing 50 leading to a receptacle 52, such as a reaction test tube. A shunt passage hereinafter to be described in detail shunts some of the reagent around the sample loop 34 to the outlet end of the loop 34 where it mixes with the sample being ejected from the sample loop 34 by the pressure of the reagent stream at the inlet end of the loop 34. In this way, the given amount of sample is simultaneously ejected from the sample loop 34, mixed with the reagent and delivered in a reagent-sample mixture to the reaction test tube 52 (analyzer). In the tube 52, the reagent reacts with the liquid sample and after a predetermined period of time the resulting mixture may be subjected to colorimetric

measurements. In the case of straight dilution, the resulting mixture may be subjected to counting, etc.

The cylinder 26 (motor) is operated to move the probe out of the cup 24 and to its retracted position and at the same time to move the valve blocks 18 and 20 relative to each other.

3. Claims 1, 20, 31-32, 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Rose et al. US 6,551,557.

Rose et al. disclose a print head that can randomly collect and deposit fluid samples to transfer the samples from a source plate to a target.

The apparatus generally comprises a ceramic tip (probe), a drop-on-demand valve (injection valve) and a positive displacement pump.

The tip is mounted and moved via a robot arm.

Referring to FIG. 7, the syringe pump 22 (probe pump) is connected to the reservoir 16 and the dispenser 12 using tubing 23 provided with luer-type fittings for connection to the syringe and dispenser. Various shut-off valves 25 (pump valve) and check valves (not shown) may also be used, as desired or needed, to direct the flow of fluid 14 to and/or from the reservoir 16 (dilutant/mobile phase), syringe pump 22 and dispenser 12.

A suitable controller can be employed to monitor and control the operation of the various components of the print head.



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4. Claims 14, 26-28, 31-32, and 35-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Tseung et al. US 2003/0099573.

Tseung et al. discloses a device that includes an X-Y-Z (probe drive system) robotic delivery system 22 that is capable of delivering bulk reagents, small supply reagents, buffer solutions, and air to the tissue specimens on the slides 12. The X-Y-Z robotic delivery system 22 includes a Z-head 24 that is controllably and selectively movable on a pair of linear motion assemblies, indicated generally by reference numerals 26a and 26b to any position in a horizontal X-Y plane. The Z-head 24 carries a vertically disposed probe 38, which is selectively and controllably movable up and down in a vertical, or Z, direction.

The device further includes an injector valve 57, a pump valve 56, and probe pump 46 (see Figure 4).

The operation of the robotic delivery system 22 is controlled by an autostainer control program implemented by the software of a control system 28. The hardware of the control system 28 is integrated into the chassis 14 of the autostainer 10 and includes a touchscreen display 30.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 30, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones.

Jones does not specifically recite the length of the connection between the injection valve and the probe or that the injection valve is limited to four or six ports.

However it would have been obvious to one of ordinary skill in the art to recognize that the connection length between the valve and probe may have been any suitable length to ensure the probe adequately extends into the sample containers.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize the number of ports may be limited as so desired by the operator. If additional testing is required or no testing at all, one may choose to add or exclude ports from the valve and employ the device for simply mixing or fluid transfer from one container to another.

8. Claims 23 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Nohl et al., US 4,957,009.

Jones does not specifically recite the length of the connection between the injection valve and the probe or that the injection valve is limited to four or six ports. Nor does Jones specify the employment of a liquid chromatography column.

Nohl et al. discloses a pushloop liquid sampling method is an improvement in the method of introducing liquid samples into test equipment (such as for liquid chromatography) via a six port valve. The method involves pulling the sample completely past the sample loop in the six port valve and then pushing the desired amount of sample back into the sample loop (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the six port valve when injecting fluids in a liquid chromatography column as taught by Nohl et al. in order to avoid errors and problems such as the introduction of bubbles within the sample loop.

9. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Munk, US 4,942,018.

Munk discloses a system for the generation of solvent composition gradients utilizes a packed bed gradient generator.

Figure 2 discloses an embodiment utilized to used to obtain a first set of experimental gradient profiles. This system was designed to generate a two-solvent gradient, and comprises a first metering pump 22 used to pump a first solvent 24 (solvent A) from a first storage reservoir 26 (reservoir A) and a second metering pump 28 used to pump a second solvent (solvent B) 30 from a second storage reservoir 32 (reservoir B) through packed bed gradient generator 10 into the sample injector 33

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chromatographic column 34 and detector 36. Both metering pumps 22 and 28 may be of conventional design and numerous such pumps are readily available on the market. For example, an LDC-Milton Roy Simplex Mini-Pump Metering Pump can be used as metering pump 22 to pump solvent A 24 from reservoir A 26 and an LDC Milton Roy Constomeric III Metering Pump can be utilized to pump solvent B 30 from reservoir B 32. Detector 36 may be any commercially available chromatographic detector such as the Spectromonitor D detector (column 5, lines 20-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Jones to incorporate the analysis column of Munk in order to identify and characterize the resultant mixture in a process in which the components of the mixture may be distinctly identified in a shorten analysis time period (column 1, lines 10-23).

10. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Heimberg et al., US 6,656,724.

Jones et al. does not disclose the probe is adjustable my comprising a drive system an X arm extending horizontally in an X direction; a Y arm slidably mounted on the X arm wherein the Y arm extends horizontally in a Y direction; and a Z arm slidably mounted on the Y arm wherein the Z arm extends vertically in a Z direction.

Heimberg et al. discloses a pipette apparatus comprising a pipette arm for pipetting sample substances and/or chemicals.

Figure 1 shows the device comprising a rectangular worksurface 2 having two face edges 2 and a front and rear longitudinal edge 4. Arranged on the worksurface 2 at its rear longitudinal edge 4 is a rear wall 6. Provided at the upper edge portion in the rear wall 6 is a horizontal rail 7 running parallel to the rear longitudinal edge 4 of the worksurface 2. Mounted traveling on the rail 7 in the longitudinal direction thereof (double-arrow 9, X direction) is a robotic arm 8.

The robotic arm 8 is arranged straight and rigid parallel to the face edges 3 of the worksurface 2, it thus standing perpendicular to the plane of the rear wall 6. The robotic arm 8 is outwardly defined by comprising two longitudinal walls 10 and a face wall 11 at its free end, the face wall being arranged U-shaped as viewed from above. Disposed between the two longitudinal walls 10 and spaced away therefrom is a rail 12. Mounted traveling on the rail 12 in the longitudinal direction thereof (Y direction) are three Z arms 13-15. Each of the three Z arms 13-15 extends vertically through a gap 16 between the rail 12 and the longitudinal side walls 10, two of the Z arms 13, 14 being arranged in the gap 16 or the like and the third Z arm 15 being arranged in the gap 16 on the right.

The robotic arm 8 is powered to travel along the rail 7 (X direction) and the Z arms 13 along (Y direction) and perpendicular (Z direction) to the rail 12 so that the Z arms 13-15 can cover substantially the complete area (X direction, Y direction) above the worksurface 2 and are height-adjustable (Z direction).

As to claim 28, as to the location of the valve it would have been obvious that the injection valve maybe located on either arm including the Z arm.

It would have been obvious to one of ordinary skill in art at the time of the invention to modify the device of Jones to incorporate the drive system of Heimberg et al. in order to allow the probe to access various size containers.

11. Claims 27, 28, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as applied to claim 14 above, and further in view of Gilson US 4,422,151 (as disclosed by applicant as the liquid handling system employed within applicant's invention, see page 4 of specification).

Jones et al. does not disclose the probe is adjustable my comprising a drive system an X arm extending horizontally in an X direction; a Y arm slidably mounted on the X arm wherein the Y arm extends horizontally in a Y direction; and a Z arm slidably mounted on the Y arm wherein the Z arm extends vertically in a Z direction.

Gilson discloses the 3-dimensional drive system as claimed by applicant including the probe holder in form of elements (26, 124).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dispensing probe system of Jones et al. by incorporating the 3-dimensional drive system of Gilson in order to allow for more mobility of the dispensing device.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sasaki, Glenn C.; Lemmo, Tony et al.; Johnson, James E. et al.; King, Howard Gregg et al.; Uffenheimer, Kenneth F. et al.; Shvets, Igor et al.; Churchill, Carl et al.; Pelc, Richard E. et al.; Richards, William et al.; Zesiger; Thierry; LaBudde;

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Edward V. et al.; Petro; Miroslav et al.; Dorenkott; Jeffrey S. et al.; Hayashi; Hidechika; Matsuyama; Sinya et al.; Meltzer; Walter; del Valle; Roberto et al.; Kaltenbach; Karl W. et al.; and Saros; Stephen disclose probe/injection devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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